REMARKS

Claims 1 to 33 are pending. Claims 1-6, 14, 17, 32 and 33 are under examination as the elected invention, and claims 7-13, 15, 16, and 18-31 have been withdrawn from consideration as being drawn to a non-elected group. In the Office action dated December 27, 2006, claims 1, 2, and 32 have been rejected and claims 3-6, 14, 17 and 33 have been objected to as depending from a rejected claim.

In this amendment, claims 1, 3-8, 10-13, 15, 16, 18-21, 24, 27, 29, 31, and 32 have been amended. Claims 2, 9, 22, and 23 have been canceled and new dependant claims 34-37 are presented.

Claims 1 and 32 have been amended to add a Markush group that recites the SEQ ID NOS. 1 to 8 which are presented in the subgroups of pending claims 3-6, which were objected to in the Office action. Claim 1 has been amended to insert the "*pagA* target" language of claim 2, which has been canceled. Claims 3-6 have been amended to depend from claim 1, instead of canceled claim 2. Withdrawn claims 7, 8, 10, 11, 12, 13, 15, 16, 18, and 19 have been amended to be dependent composition claims which ultimately depend from claim 1, and to add language clarifying which oligonucleotide is referred to in dependent claims 11, 13, 15, 16, 18, and 19. Withdrawn claim 20 has been amended consistent with amended claim 1 to add SEQ ID Nos. 1 to 8, and withdrawn dependent claims 21, 24, 27, 29, and 31 have been amended, all with the intention of rejoining the process claims if patentable subject matter is found in the composition claims. Claims 2, 9, 22, 23, and 33 have been canceled. New claims 34-37 are presented which depend from pending amended claim 32 and refer to elements presented in amended claims 8, 11, 13, and 31. Applicants believe that these claims are supported by the disclosure, including subject matter presented originally in canceled claims 9, 23 and 33, and no new subject matter has been added. Applicants request entry of these amendments and reconsideration of this application.

Rejections under 35 U.S.C. § 102(e)

The rejection of claims 1 and 32 under 35 U.S.C. § 102(e) as allegedly anticipated by Lee et al., US Patent No. 6,770,479, has been maintained. Claims 1 and 32 have been amended as suggested by the Examiner. Applicants respectfully request withdrawal of the rejections under § 102(e) and seek

allowance of claims 1 and 32.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1, 2, and 32 stand rejected based on new rejections raised under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the enablement requirement. The Examiner's view was that the claims are drawn to "unlimited hybridizing and complementary polynucleotides" because the conditions and/or complementary sequences are not limited, leading to the conclusion that "one of ordinary skill in the art would be forced into undue experimentation to practice the claimed invention." Claim 2 has been canceled, so the rejection of claim 2 is moot. Applicants respectfully traverse the rejections of claims 1 and 32 based on the amendments to claims 1 and 32 and disclosure in the specification that would allow a person of ordinary skill in the art to practice the invention by using only routine experimentation, not undue experimentation.

In determining what constitutes undue experimentation, a standard of reasonableness with due regard for the nature of the invention and state of the art is applied. Factors considered in making this determination include the: (1) quantity of experimentation needed, (2) guidance presented in the specification, (3) presence or absence of working examples in the disclosure, (4) nature of the invention, (5) state of the prior art, (6) relative skill of those in that art, (7) predictability of the art, and (8) claim breadth. *Ex Parte Forman*, 230 U.S.P.Q. 546, 547 (Bd. App. 1986). The level of skill in the art of molecular biology has been recognized as quite high. *Id.* at 548.

Claims 1 and 32 have been amended to insert the oligonucleotide SEQ ID Nos. 1 to 8, which were presented in subgroups in claims 2 to 6, to change the minimum oligonucleotide size to 25 nucleotides, which is consistent with the sizes of SEQ ID Nos. 1, 5, and 6, and to insert "substantially" before "complementary" which is supported at page 10, lines 4 to 8. Applicants respectfully submit that the definition of "substantially complementary" provided in the specification, together with other information provided in the specification discussed below, excludes the interpretation of "complementarity of even a single nucleic acid residue" or "only two or three nucleic acid residues that are complementary" that was

used in the rejection of claims 1 and 32 (Office action, page 4, lines 18 to 23 and page 5, lines 5 to 8).

Applicants respectfully disagree with the assertion that "one of ordinary skill would be forced into undue experimentation to practice the claimed invention" for the following reasons. Claims 1 and 32 specify a limited number of definite target sequences, specify size lengths of the synthetic oligonucleotides that hybridize specifically to a specified target sequence, and specify that at least one of the synthetic oligonucleotides be selected from among SEQ ID Nos. 1 to 8. Nucleic acids that are "complementary" are described in the specification at page 9, line 28 to page 10, line 16, and appropriate hybridization conditions were well known to those of ordinary skill in the art at the time the invention was made, e.g., as described at page 10, line 16 to page 11, line 2. Given the specific and definite target sequences disclosed in the specification, the sizes of the synthetic oligonucleotides, and the characteristic that they hybridize specifically to an intended target sequence, a person of ordinary skill in the art of molecular biology could readily determine whether an oligonucleotide was included in the claimed invention and could determine merely by using routine practices that the oligonucleotide specifically hybridizes to the intended target sequence. For example, the skilled person could use any of the information and methods described by Sambrook et al., *Molecular Cloning, A Laboratory Manual*, (2nd Ed., 1989), pp. 1.90-1.91, 7.37-7.57, 9.50-9.51, 11.12-11-13, and 11.47-11.57, cited in the specification at page 10, lines 18 to 20. The specification provides additional guidance to allow a person of ordinary skill in the art of nucleic acid hybridization to determine whether an oligonucleotide would hybridize specifically to its intended target based on the concept of "Tm" which was well known in the art at the time the invention was made, as described at page 13, lines 5 to 13 of the specification. Selection and testing of probes for specific hybridization to an intended target would use skills and methods known to those of ordinary skill in molecular biology as described in the specification at page 13, lines 14 to 27 (which cites Sambrook et al., *Id.* at 11.45-11.57). Further description of hybridization conditions and methods appear in the specification at page 19, line 29 to page 20, line 22, and in the working examples at page 26, line 29 to page 42, line 23. Based on the definite target sequences specified in claims 1 and 32, the sizes of the synthetic oligonucleotides specified in claims 1 and 32, and the guidance provided in the specification including the working examples, a person of ordinary skill in the art of molecular biology would use methods well known

in the prior art to select an oligonucleotide sequence in the specified size range that is substantially complementary to the intended target, would employ well known methods based on Tm to predict those oligonucleotides expected to hybridize specifically to the intended target, and use routine testing to confirm that a synthetic oligonucleotide hybridizes specifically to the intended target.

The requirements of 35 U.S.C. § 112, first paragraph do not preclude routine testing by using skills that a person of ordinary skill in the art would have and methods that the person of ordinary skill in the art would practice. That is, routine testing does not equate with "undue experimentation." Based on the specific elements included in claims 1 and 32 which define a finite set of oligonucleotides, the guidance presented in the specification, including multiple working examples, the state of the prior art, including the ability to predict oligonucleotide sequences expected to hybridize specifically to a particular intended target sequence, the high level of skill possessed by a person of ordinary skill in the field of molecular biology, and the routine nucleic acid hybridization testing needed to assess the performance of oligonucleotides for characteristics similar to those described in the working examples, Applicants respectfully submit that "undue experimentation" would not be required to practice the inventions of claims 1 and 32. Therefore, Applicants traverse the rejections under 35 U.S.C. § 112, first paragraph and request reconsideration and allowance of amended claims 1 and 32.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims, as amended, are patentable and in condition for allowance. Accordingly, withdrawal of the rejections and allowance of the application is earnestly solicited. The undersigned has made a good-faith effort to address all the points raised in this Office Action and to place the claims in condition for allowance. If minor matters remain, however, that could be resolved by a telephone interview, the Examiner is invited to contact the undersigned at the number below.

Applicants believe that no fee is due in connection with filing this amendment, but if that is incorrect, then authorization is hereby provided to debit any fees associated with filing of this amendment from the USPTO deposit account number 07-0835 maintained by Gen-Probe Incorporated.

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being filed electronically, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.

Respectfully submitted,

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